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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/244,792 02/05/99 IACONO

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BAKER & BOTTS  
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NEW YORK NY 10112

HM12/0628

EXAMINER

TRAVERS, R

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/244,792

Applicant(s)

Iacono

Examiner

RUSSELL TRAVERS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 13, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-48 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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The amendment filed April 13, 2001 has been received and entered into the file.

Applicant's arguments filed April 13, 2001 have been fully considered but they are not deemed to be persuasive.

Claims 19-48 are presented for examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

*Done*  
*102*  
Claims 19, 22, 25, 29, 30, 35, 38, 40-42, 44, 46 and 47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gilbert et al, or Adjei et al, both of record.

Claims 21, 27, 30, 32, 38, 40-41, 43- 44 and 46-47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Knight et al or Waldrep et al, of record.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 20-48 are rejected under 35 U.S.C. § 103 as being unpatentable over Adjei et al and Waldrep et al, in view of Gilbert et al, Knight et al and Applicant's admission on the record.

Adjei et al, Waldrep et al, Gilbert et al, Knight et al and Applicant admits on the record the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating graft rejection, inflammation and those conditions herein claimed and disclosed. Claims 22, 23, 24, 27, 29, 33, 34, 42 and 45, and the primary references, differ as to:

- 1) recitation of various un-encapsulated dosage forms, and,
- 2) dosage levels herein claimed.

Attention is directed to Adjei et al, Waldrep et al, Gilbert et al and Knight et al teaching the various encapsulated, and organic solvent aerosol formulations as an improvement over simple aerosol employment of the powdered active ingredient. Examiner cited prior art teaches powdered cyclosporine as useful for an anti-

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inflammation, and anti-rejection medicament administered by aerosol. The skilled artisan would have possessed all conventional administration regimens, and seen the selection of one or another as the simple selection from among obvious alternatives. In the instant case, this selection process need not be reached. Adjei et al, Waldrep et al, Gilbert et al and Knight et al teach cyclosporine as useful by aerosol administration, as herein claimed. It is noted that Adjei et al, Waldrep et al, Gilbert et al and Knight et al recite the use of unencapsulated cyclosporine administered by aerosol inhalation; although this method is not claimed.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. Attention is directed to Adjei et al (column 8) teaching the normal practice of dosage maximization by the attending medical professional. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed compositions and therapeutic methods.

Claim 47 specifically requires a pharmaceutical composition wherein the particle size is 0.1-2.0 microns. Adjei et al teach particle sizes encompassing this claimed range.

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Claim 43 requires propylene glycol carrier or excipient to administer the active ingredients. This carrier is taught as old and well known by Waldrep et al (see column 4, line 59).

Attention is directed to claims reading on cyclosporine powder, at a particular size range, absent carriers or excipients. Such claims read on the compounds herein disclosed, and taught as old by the Examiner cited prior art.

### **RESPONSE TO ARGUMENTS**

As stated above, Adjei et al, Waldrep et al, Gilbert et al and Knight et al teach encapsulation as an improvement over simple powder aerosol administration; making statements to these facts. Additionally, Examiner takes notice of phosphatidylcholine as an "organic solvent". Waldrep et al also teach Applicants' organic solvent as useful for the instant claimed utility.

As stated above, Adjei et al, Waldrep et al, Gilbert et al and Knight et al teach encapsulated cyclosporine as an improved aerosol delivery system. Examiner cited prior art also teaches the optimal particle size and requisite dosage. In the instant case, Applicant is attempting to recapture the state of the art superseded by Adjei et al, Waldrep et al, Gilbert et al and Knight et al.

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Applicants aver unexpected benefits residing in the claimed subject matter, yet fail to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). Applicants have not provided data illustrating unexpected benefits residing in the recited subject matter reasonably commensurate in scope with the instant claims. Absent claims commensurate with a showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant carriers and excipients are not employed concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to *In re Graf*, 145 USPQ 197 (CCPA 1965) and *In re Finsterwalder*, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Examiner would favorably consider claims directed to those medicaments providing unexpected therapeutic benefits, as averred herein.

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Examiner cited prior art teaches the claimed compounds alone, or with simple carriers as useful for treating those graft rejections herein claimed. Failure to claim such simple and fundamental medicament administration procedures fail to diminish those teachings. Additionally, Applicant appears to be arguing a much more limited invention than herein claimed; rebuttal arguments based on unclaimed limitations are moot. If medicament application produces an expected therapeutic outcome, that therapeutic outcome is anticipated; regardless the recitation of that inherent therapeutic benefit.

The instant claims are directed to employing an organic solvent, a very broad carrier recitation for such a crowded field. A simple oil, or those ingredients employed for encapsulation, would meet an "organic solvent" limitation.

As stated above, the discovery of a mechanism by which a drug is taken up by a biological system fails to distinguish over the same administration system before such discoveries.

Applicant's claims administered in an "organic solvent" read on any organic carrier, such as liposomes, or dry powder carried by air. Attention is directed to Waldrep et al teaching dry particle cyclosporine administration (see column 1), or "organic solvents" (ethanol, or propylene glycol). Applicant's presented claims are extremely broad, thus, are easily met by the Examiner cited prior art. Those inventions argued appear to be much more limited than those claims presented. Examiner can not



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read limitations from the specification into the presented claims. Only limitations specifically recited in the presented claims will serve to distance the envisioned invention from the cited prior art.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



**Russell Travers**  
**Primary Examiner**  
**Art Unit 1617**